REMARKS

Claims 1-34 are pending in the application. No amendments, cancellations, or additions to the claims have been made by this Response. No new matter has been added.

Prior Art Rejections

Claims 1-4,6-13, 27, and 28 stand rejected under 35 USC 102(e) in view of Nohl et al. ("Nohl"), US 6,390,088. Claim 5 stands rejected under 35 USC 103(a) in view of Nohl. Claims 14-26 and 29-34 stand rejected under 35 USC 103(a) in view of Nohl in combination with Rand ("Rand"), US 6,474,331.

A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference. MPEP 2131. Further, to establish a *prima facie* case of obviousness, [...] the prior art reference (or references when combined) must teach or suggest all the claim limitations. MPEP 2143.

With regard to the rejections under 35 USC 102(e), the Office has failed to show that at least one claimed element of the invention is disclosed by the cited references. Referring to independent claims 1 and 27, the references do not disclose an oral inhaler having a mouthpiece with at least one longitudinally-extending disuniformity as recited:

> Claim 1: An oral inhaler suitable for delivering a pharmaceutical formulation to a patient, said inhaler comprising:
>
> a container having the pharmaceutical formulation comprising at least one medicament present therein; and
>
> a mouthpiece configured for oral engagement with a patient and in communication with said container, the mouthpiece having an inner surface and an outer surface;
>
> wherein the outer surface of the mouthpiece contains at least one longitudinally-extending disuniformity such that when the patient orally engages the mouthpiece at least one void space is created between the outer surface of the mouthpiece and the oral cavity of the patient so as to provide an air flow channel through the at least one void space to facilitate intake of the at least one medicament by the patient.

> Claim 27: An oral inhaler system for delivering a pharmaceutical formulation to a patient, said inhaler comprising:
>
> a container having the pharmaceutical formulation comprising at least one medicament present therein, the at least

> one medicament selected from the group consisting of analgesics, anginal preparations, antiinfectives, antihistamines, anti-inflammatories, antitussives, diuretics, hormones, therapeutic proteins and peptides, and combinations thereof; and
>
> a mouthpiece configured for oral engagement with a patient and in communication with said container, the mouthpiece having an inner surface and an outer surface;
>
> wherein the outer surface of the mouthpiece contains at least one longitudinally-extending disuniformity such that when the patient orally engages the mouthpiece at least one void space is created between the outer surface of the mouthpiece and the patient so as to provide an air flow channel through the at least one void space to facilitate intake of the at least one medicament by the patient, wherein the at least one longitudinally-extending disuniformity is selected from the group consisting of at least one protrusion, at least one indentation, at least one opening in the outer surface of the mouthpiece, and combinations thereof.

The Office asserts that the recited mouthpiece is anticipated by Figures 2 and 3 of Nohl. Specifically, the Office points to item (7) of Nohl as anticipating the recited longitudinally-extending disuniformities.

A close reading of Nohl reveals that item (7) is not a longitudinally-extending disuniformity, as claimed. Rather, item (7) refers to a single channel disposed within the disclosed mouthpiece through which aerosol is delivered to a patient. Applicant's interpretation of item (7) is supported by the Nohl specification and claims -

> The inhaler 1 according to the invention comprises a supply container 2 for an aerosol. In the present case the supply container 2 is detachably connected to a housing which has a mouthpiece 6 with air channel 7 extending *therein*. By means of an actuating element (not shown here) a dose of the aerosol is inlet from the supply container 2 into the nozzle 4 where it is atomized. The patient breathes in this atomized aerosol through *the* air channel 7.
> (Emphasis added) (Nohl, col. 5, l. 62 – col. 6, l. 2)

With regard to the rejections under 35 USC 103(a), other than item (7) as addressed above, the Office does not assertthat any portion of Nohl or Rand, alone or in combination, teach, suggest, or motivate one of skill in the art to construct an oral inhaler with disuniformities as claimed in the instant application. If anything, Nohl teaches away from the claimed disuniformities,

since the channel of Nohl is designed for a patient to breathe atomized aerosol through (Nohl, col. 6, ll. 1-2) while Applicant's claimed at least one disuniformity provides a void space between the contact surfaces of the oral cavity of a patient and the outer surface of the mouthpiece (p. 5, ll. 23-26) such that the patient is advantageously allowed to inhale freely during dose delivery without an airflow path internal to the inhalation device or an additional mouthpiece component being required (p.12 , l.32 – p.13 , l.3).

Whereas the cited references fail to disclose, teach, or suggest each of the recited claim recitations, Applicant respectfully submits that the pending 102 and 103 rejections should be withdrawn, and such action is respectfully requested.

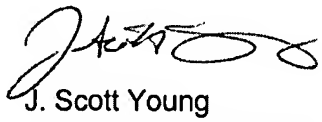
Conclusion

In view of the remarks made above, Applicant respectfully submits that the application is in condition for allowance, and such allowance is respectfully requested.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge any fees or credit any overpayment, particularly including any fees required under 37 CFR Sect 1.16 or 1.17, and any necessary extension of time fees, to deposit Account No. 07-1392.

The Examiner is invited to contact the undersigned at (919) 483-8160, to discuss this case, if desired.

Respectfully submitted,



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